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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,189	06/03/1999	MASATAKA KINJO	990360/LH	2516

1933 7590 08/14/2002

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NEW YORK, NY 10017-2023

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/14/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,189

Applicant(s)

KINJO, MASATAKA

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-39, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 9-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 39, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detail Action*.

Art Unit: 1637

Response to Amendment

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

1. The amendment filed 6/6/2002 has been entered.
2. The rejection of claims 2-8 and 39-43 under 35 U.S.C. §112, second paragraph is withdrawn because of the amendment.
3. The rejection of claims 1-8 and 39 under 35 U.S.C. §102(e) as being anticipated by Eigen et al. (5,807,677) is withdrawn because of the amendment.
4. The rejection of claims 1-8 and 39 under 35 U.S.C. §103(a) over Eigen et al. as applied to claims 1-8 and 39 above and further in view of Gyllensten et al. is withdrawn because of the amendment.

The New Grounds of Rejections

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1637

6. Claims 1-5, 7-8, 39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eigen et al. (5,807,677), and in view of Gyllensten et al. (Proc. Natl. Acad. Sci. USA, 1988, Vol. 85, pg. 7652-7656) and Wang et al. (5,567,583).

Eigen et al. disclose a method for the direct identification of single nucleic acid strands of a specific target sequence (See the Abstract). The method involves fluorescence correlation spectroscopy (FCS) in which the target nucleic acid is amplified with PCR (See column 3, lines 46-57). This is inherent that a forward primer and a reverse primer are used in the reaction as recited in the limitation of claim 1(a) and the primer is marked with one or more dye molecules (See column 2, lines 31-32 and column 4, lines 25-28) (as recited in claim 39). This is also inherent that the number of labeled primer molecules is known (as recited in claim 39). The fluorogenic molecules can be measured in extremely diluted solution (See column 2, lines 39-42). Eigen et al. also disclose that alternatively, it is also possible to produce the dyed double strand of nucleic acid to be identified through a direct polymerization of the nucleic acid strand to be identified, whereby dyed nucleic acid mononucleotides are used and marked UTP's are preferably used (See column 5, lines 54-59) (See the specification, pg. 467, lines 5-8).

The teachings of Eigen et al. do not disclose using asymmetric nucleic acid amplification.

Gyllensten et al. disclose using asymmetric amplification to amplify a single copy gene (See pg. 7652, the Abstract). The ratio of the primer used is 50:0.5, 50:5 and 50:50 (see pg. 7654, column 2, second paragraph).

Art Unit: 1637

Gyllensten et al. do not disclose the primer which has low concentration is labeled

One of ordinary skill in the art would have been motivated to combine the teachings of Eigen et al. and Gyllensten et al. because the fluorescence correlation spectroscopy (FCS) can be used directly for both single-stranded and double stranded nucleic acid molecules and the method is more direct, identifying the individual nucleic acids which leads to a noticeable difference in the time required (See column 3, lines 46-57) and the amplification step by using asymmetric nucleic acid amplification as taught by Gyllensten et al. produces an excess of full-length single-stranded DNA of a chosen strand that is suitable for sequence determination (See pg. 7652, first paragraph). Further, Wang et al. indicate that the optimal primer ratio for asymmetric amplification is a factor to be determined empirically (See column 8, lines 13-15). One of ordinary skill in the art would have also labeled the primer which has a low concentration in the reaction because labeling a primer was well known in the art at the time of the instant invention to differ greatly from the free primers in both their charge characteristics and their mobility and can be directly detected by FCS (See column 2, lines 30-38 of the reference of Eigen et al.). It would have been prima facie obvious to carry out the method as claimed.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

Art Unit: 1637

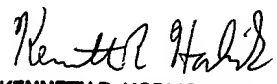
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 31 2002


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/7/02